

ABSTRACT FORM

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Treatment of hepatocellular carcinoma and colon cancer with tumor vaccines generated by a two-step process; a phase I/II clinical trial. Wu, S.G., Zhao, J., Xie, T.P., Shen, F., Liu, Y.J., Wang, H., Wei, L.X., Trojan, J., Anthony, D.D., Habib, N., Wu, M.C. and Guo, Y.J. First and Second Military Medical University, P.R. China. The University Hospitals of Cleveland, Cleveland, OH 44106, Hammersmith Hospital, London, UK and Sidney Kimmel Cancer Center, San Diego, CA 92121, USA. Tumor cells when treated with a combination of cytokines and then, armed *in vitro* with bispecific Mabs became more immunogenic and can cure established hepatoma and colon carcinoma in both mouse and rat model systems. To evaluate clinical effectiveness of the cellular vaccines on treatment of human hepatocellular carcinoma(HCC) and colon cancer, we generated human cellular vaccines using this two-step process and treated 13 HCC patients and 5 colon cancer patients. In HCC patients, stages were II in 3, III in 7, and IV in 3 and in colon cancer patients, all had distant metastasis. All treated patients had a pathological diagnosis. Each patient had received subcutaneous injection of $1-1.5 \times 10^7$ tumor vaccines for two times within a two week period. Fifteen patients experienced a 37.8-38.6°C fever after the second injection that continued for 8 to 15 hours. There were no other toxic and allergic reactions. DTH reactions to autologous tumor cells were significantly increased in 11 of 18 patients. Two patients had complete regression of metastatic lesions and four patients had partial regression of metastasis after treatment. Primary tumor regression >30% in size occurred in four HCC patients. In two patients with significantly tumor regression, tumors became operable and were successfully excised. Histopathology demonstrated marked necrosis and abundant lymphocyte infiltration in tumor tissues. The results suggest that the cellular vaccines generated by this two-step process are safe and may provide a useful immunotherapeutic strategy for human cancers.

Appendix A